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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,281	10/13/2000	Hyun Kim	GI 5387	9127

7590 01/10/2002

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EXAMINER
GUTTMAN, HARRY J

ART UNIT	PAPER NUMBER
1651	8

DATE MAILED: 01/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/687,281	KIM ET AL.	
	Examiner	Art Unit	
	Harry J Guttman	1651	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims and Application

Claims 1-7 are pending.

The Response with amendment filed November 19, 2001 was received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-7 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Response argues that the description in the specification describes sufficiently what is meant by the terms "pore forming agent" and "derivative", and that these terms are not ambiguous to one skilled in the art.

These terms are only exemplified in the specification. They have not been defined in the specification and as such there is no clear definition of what these terms mean, even to one skilled in the art. Could EDTA, EGTA, an ionophore or a drill bit be considered a pore forming agent? Could a piece of mucus be a HA derivative? These

terms do not sufficiently define the metes and bounds of the corresponding elements in the claims.

Applicant's arguments filed November 19, 2001 have been fully considered but they are not found persuasive for the reasons of record and for the reasons above.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vanis et al. (CZ 283073).

The Response argues that Vanis et al. do not disclose an injectable composition. However, Vanis et al. (CZ 283073) disclose a mixture comprising calcium phosphate, hyaluronic acid and BMP (abstract). A mixture is a formable paste that is injectable. A paste while capable of forming shapes can still be injectable, much like icing through a pastry bag or caulk through a caulk gun.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wozney et al. (US 6187742).

The Response argues that Wozney et al. do not the combination of elements, and that it is not taught as injectable.

Wozney et al. (US 6187742) do clearly teach the combination of osteogenic proteins (including BMP-7, which is OP-1, and preferably BMP-2; column 3 lines 26-50)) with a number of carriers including porous particulate polymers (including PEG; column 4 line 59- column 5 line 5), sucrose (column 5 lines 40-42), hyaluronic acid and tricalcium phosphate (column 5 lines 50-56). Wozney et al. discuss the use of the preparation by injection through a syringe (column 5 line 63).

There is no explicit exemplification of the combination of these elements as instantly claimed.

However, it would have been obvious to one of ordinary skill in the art to choose from the list provided in the cited reference for each of the category of substances as described in the cited reference.

Claims 1, 2 and 4-7 stand rejected 35 U.S.C. 103(a) as being unpatentable over Rhee et al. (US 5752974).

The Response argues that Rhee et al. do not disclose the claimed invention.

Rhee et al. (US 5752974) do disclose the combination of BMP-2 or BMP-7 (column 7 lines 15-19), PEG (column 5 line 5-8), a crosslinked hyaluronic acid (column 5 lines 51-55) or hyaluronic acid (column 6 lines 31-34), and tricalcium phosphate (column 6 lines 50-57). This combination is designed for injection (column 8 lines 56-64, and column 9 lines 50-53).

There is no explicit exemplification of the combination of these elements as instantly claimed.

However, it would have been obvious to one of ordinary skill in the art to choose from the list provided in the cited reference for each of the category of substances as described in the cited reference.

Claims 1-5 and 7 stand rejected 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5939323).

The Response argues that Valentini et al. (US 5939323) do not disclose an injectable composition as claimed.

Valentini et al. (US 5939323) disclose the combination of esterified hyaluronic acid (column 5 lines 32-48), NaCl (column 6 lines 4-19), and BMP (including BMP-2; column 6 line 34-38, and example 6). These can be solutions mixed prior to the formation of the scaffold which include bioactive molecules including BMPs (column 6 line 63 to column 7 line 6) and use of BMP2 is exemplified in examples 4 and 6. Solutions are injectable compositions.

There is no explicit exemplification of the combination of these elements as instantly claimed.

However, it would have been obvious to one of ordinary skill in the art to choose from the list provided in the cited reference for each of the category of substances as described in the cited reference.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of objective evidence to the contrary.

Applicant's arguments filed November 19, 2001 have been fully considered but they are not found persuasive for the reasons of record and for the reasons above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Harry J. Guttman, Ph.D. at telephone number (703) 305-0159. The examiner can normally be reached during the hours of 07:30 to 16:00 Eastern Time, Mon.-Thurs. If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number for Art Unit 1651 is (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

All internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified or exchanged unless there is of record an express waiver of the confidentiality requirements of 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published in the Patent and Trademark Office Official Gazette on 25 February 1997 at 1195 OG 89.

H.J.G. 7 January 2002

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